

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT  
INFRINGEMENT LITIGATION

)  
)  
)  
)

C.A. No. 05-356-KAJ  
(consolidated)

**NOTICE OF DEPOSITION AND SUBPOENA OF  
APOTEX INC. PURSUANT TO  
FEDERAL RULE OF CIVIL PROCEDURE 45**

**PLEASE TAKE NOTICE** that, pursuant to Rule 45 of the Federal Rules of Civil Procedure, plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc. (collectively, "Janssen") will take the deposition upon oral examination of Apotex Inc. at the offices of Ashby & Geddes, 222 Delaware Avenue, 17<sup>th</sup> Floor, Wilmington, Delaware 19801 beginning at 9:00 A.M. on June 13, 2006.

NOTICE IS FURTHER GIVEN THAT the deposition will be recorded stenographically through instant visual display of testimony (real-time), by certified shorthand reporter and notary public or such other person authorized to administer oaths under the laws of the United States, and shall continue from day to day until completed. This deposition will be videotaped.

NOTICE IS FURTHER GIVEN THAT pursuant to the Federal Rules of Civil Procedure, Janssen will serve upon Apotex Inc. a Subpoena in a Civil Case. Attached hereto as Exhibit A is a true and correct copy of that Subpoena.

ASHBY & GEDDES

*/s/ Tiffany Geyer Lydon*

---

Steven J. Balick (I.D. #2114)  
John G. Day (I.D. #2403)  
Tiffany Geyer Lydon (I.D. #3950)  
Lauren E. Maguire (I.D. #4261)  
222 Delaware Avenue, 17<sup>th</sup> Floor  
P.O. Box 1150  
Wilmington, DE 19899  
(302) 654-1888

*Attorneys for Janssen Pharmaceutica N.V., Janssen,  
L.P., and Synaptech, Inc.*

Dated: May 30, 2006

169953.1

# **EXHIBIT A**

A088 Subpoena in a Civil Case

Issued by the  
**United States District Court**  
**DISTRICT OF DELAWARE**

IN RE: '318 PATENT INFRINGEMENT  
 LITIGATION

**SUBPOENA IN A CIVIL CASE**

Case Number:<sup>1</sup> C.A. No. 05-356-KAJ (consolidated)  
 (District of Delaware)

TO: Apotex Inc.  
 c/o The Corporation Trust Company  
 Corporation Trust Center, 1209 Orange Street  
 Wilmington, DE 19801

- ☐ YOU ARE COMMANDED to appear in the United States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

- ☒ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case. Please See Schedule A Attached

PLACE OF DEPOSITION Recording Method: By stenographer and videotape	DATE AND TIME
Ashby & Geddes, 222 Delaware Avenue, 17th Floor, Wilmington, DE 19899	JUNE 13, 2006, 9:00 A.M.


- ☐ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects): Please See Schedule B Attached

PLACE	DATE AND TIME

- ☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT) Attorney for Plaintiffs Janssen Pharmaceutica N.V., Janssen L.P., and Synaptech, Inc. 	DATE AND TIME May 30, 2006
ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER Tiffany Geyer Lydon, Ashby & Geddes 222 Delaware Avenue, 17th Floor Wilmington, DE 19899 Tel: 302-654-1888	

(See Rule 45, Federal Rules of Civil Procedure, Parts C&D on next page)

<sup>1</sup> If action is pending in district other than district of issuance, state district under case number.

A088 Subpoena in a Civil Case

**PROOF OF SERVICE**

DATE	PLACE
SERVED	
SERVED ON (PRINT NAME)	MANNER OF SERVICE
SERVED BY (PRINT NAME)	TITLE

**DECLARATION OF SERVER**

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on \_\_\_\_\_ DATE \_\_\_\_\_ SIGNATURE OF SERVER \_\_\_\_\_

ADDRESS OF SERVER \_\_\_\_\_

**Rule 45, Federal Rules of Civil Procedure, Parts C&D****(c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.**

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction which may include, but is not limited to, lost earnings and reasonable attorney's fee.

(2)(A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(2)(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to compel production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3)(A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

- (i) fails to allow reasonable time for compliance,
- (ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to

the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or

(iv) subjects a person to undue burden

(3)(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena, or, if the party in who behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

**(d) DUTIES IN RESPONDING TO SUBPOENA.**

(1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

**SCHEDULE A**

**DEFINITIONS**

1. As used herein, “the ‘318 patent” shall mean United States Patent No. 4,663,318.
2. As used herein, “ANDA” shall mean Abbreviated New Drug Application Number 77-781.
3. As used herein, “Plaintiffs” refers to Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc., either individually or collectively.
4. As used herein, “You,” “Your,” or “Yours,” shall mean Apotex Inc., Apotex Inc.’s corporate predecessors and past or present subsidiaries, affiliates, divisions, departments, officers, directors, principals, agents, employees and any individuals or entities that at any time have acted or purported to act on behalf of Apotex Inc. or its successors.

**TOPICS**

1. The notice You sent to Plaintiffs on August 26, 2005, attached hereto as Exhibit 1.
2. Your patent certification regarding the ‘318 patent in connection with ANDA No. 77-781.

# **EXHIBIT 1**



August 26, 2005

Janssen Pharmaceutica Products, L.P.  
1125 Trenton-Harbourton Road  
Titusville, NJ 08560-0200

Attention: Patent Counsel

and

Janssen Pharmaceutica N.V.  
C/o Johnson and Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003

Attention: Mary A. Appolina

Dear Sirs:

Re: Apotex ANDA for Galantamine Hydrobromide Tablets  
Notice Certification of Noninfringement of U.S. Patents No. 6099863 and  
6358527  
Offer of Confidential Access to Application

---

As required by Sections 505(j)(2)(B)(i) and (ii) of the Federal Food, Drug and Cosmetic Act ("Act") (21 U.S.C. § 355(j)(2)(B)(i), (ii)), notice is hereby given to you, that the Food and Drug Administration has received an Abbreviated New Drug Application ("ANDA") submitted by Apotex.

In accordance with 21 C.F.R. § 314.95, the following information is hereby provided:

- The ANDA contains the required bioavailability or bioequivalence data.
- The ANDA number for the application is 77-781.
- The established name for the proposed drug product is Galantamine Hydrobromide Tablets.



- The active ingredient, strength, and dosage form of the product are as follows: galantamine hydrobromide in strengths equivalent to 4 mg, 8 mg, and 12 mg galantamine per tablet.

With its ANDA, Apotex has submitted a "paragraph IV certification", pursuant to Sections 505(j)(2)(A)(vii)(IV) of the Act (21 U.S.C. § 355(j)(2)(A)(vii)(IV)), that its proposed tablets will not infringe patents 6099863 and 6358527.

In accordance with 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. §§ 314.95(c)(6)(i), (ii), the factual and legal bases for the paragraph IV certification and the statement that the patents will not be infringed is set forth below.

Furthermore, in accordance with 21 U.S.C. § 355(j)(5)(C)(i)(III), as amended by Title XI of the Medicare Prescription Drug, Improvement and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003), this notice letter also includes, and Apotex hereby extends, an "Offer of Confidential Access to Application" to you under the specific restrictions set forth below in Section III of this letter.

All claims of both patents are limited to a tablet comprising a carrier which comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose as diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.

Our tablets will not infringe because:

1. They do not comprise a spray-dried mixture of lactose monohydrate and microcrystalline cellulose. More particularly, they do not comprise a spray-dried ingredient at all, or any lactose at all; and
2. They do not comprise an insoluble or poorly soluble cross-linked polymer disintegrant. More particularly, they do not comprise any cross-linked polymer at all, and the only disintegrant that they comprise is starch.

Apotex affirmatively states that it may have further basis, in addition to those stated above, supporting its noninfringement positions, and further that additional basis bearing on the validity, noninfringement, and/or enforceability of the patents may develop in the event of litigation between the parties. Apotex expressly reserves the right to assert additional defenses and grounds bearing on the validity, noninfringement, and/or enforceability of the patent in the even of litigation between the parties.

Receipt of this notice begins the 45-day period provided for in Section 505(j)(5)(B)(iii) of the Hatch-Waxman Amendments to the Federal Food, Drug



and Cosmetic Act. The ANDA will be amended with a copy of the return receipt for this notice, as required by 21 C.F.R. § 314.95(e).

The following person is authorized to accept service of process on behalf of Apotex:

Ms. Tammy McIntire  
Apotex Corp.  
2400 N. Commerce Parkway  
Suite 400  
Weston, FLA 33326

Pursuant to 21 U.S.C. § 355 (j)(5)(C), as amended by Title XI of the Medicare Prescription Drug, Improvement and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003), this notice letter includes an Offer of Confidential Access to Application. As required by § 355(j)(5)(C)(i)(III), and pursuant to certain restrictions described below, Apotex offers to provide you with confidential access to certain information from its ANDA for the sole and exclusive purpose of determining whether an infringement action referred to in § 355(j)(5)(B)(iii) can be brought.

Section 355(j)(5)(C)(i)(III) allows Apotex to impose restrictions "as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protection order been entered for the purpose of protecting trade secrets and other confidential business information." That provision also grants Apotex the right to redact its ANDA in response to a request for Confidential Access under this offer.

As permitted by statute, Apotex imposes the following terms and restrictions on its Offer of Confidential Access:

- 1) Apotex will permit confidential access to certain information from its proprietary ANDA to attorneys from one (1) outside law firm representing you; provided, however, that such attorneys do not engage, formally or informally, in patent prosecution for you. Such information (hereinafter, "Confidential Apotex Information") shall be marked with the legend "CONFIDENTIAL".
- 2) The attorneys from the outside law firm representing you shall not disclose any Confidential Apotex Information to any other person or entity, including your employees, outside scientific consultants, and/or other outside counsel retained by you, without the prior written consent of Apotex.



- 3) As provided by § 355(j)(5)(C)(i)(III), your outside law firm shall make use of the Confidential Apotex Information for the sole and exclusive purpose of determining whether an action referred to in § 355(j)(5)(B)(iii) can be brought and for no other purpose. By way of example only, the Confidential Apotex Information shall not be used to prepare or prosecute any further or pending patent application by you, or in connection with any filing to, or communication with, the FDA relating to Apotex' ANDA. Your outside law firm agrees to take all measure necessary to prevent unauthorized disclosure or use of the Confidential Apotex Information, and that all Confidential Apotex Information shall be kept confidential and not disclosed in any manner inconsistent with this Offer of Confidential Access. Your outside law firm further agrees never to use Confidential Apotex Information, directly or indirectly, in competition with Apotex, nor will it allow any other person or entity to do so.
- 4) The Confidential Apotex Information disclosed is, and remains, the property of Apotex. By providing the Confidential Apotex Information, Apotex does not grant you and/or your law firm any interest in or license for the Confidential Apotex Information.
- 5) Your law firm shall, within thirty-five (35) days from the date that it first receives the Confidential Apotex Information, return to Apotex all Confidential Apotex Information and any copies thereof. Your law firm shall return to Apotex all Confidential Apotex Information before any infringement suit is filed by your, if suit is commenced before this 45-day period expires. In the event that you opt to file suit, none of the information contained in or obtained from any Confidential Apotex Information that Apotex provides will be included in any publicly-available complaint or other pleading.
- 6) Nothing in this Offer of Confidential Access shall be construed as an admission by Apotex regarding the validity, enforceability, and/or infringement of any U.S. Patent. Further, nothing herein shall be construed as an agreement or admission by Apotex with respect to the competency, relevance, or materiality of any such Confidential Apotex Information, document, or thing. The fact that Apotex provides Confidential Apotex Information upon your request shall not be construed as an admission by Apotex that such Confidential Apotex Information is relevant to the disposition of any issue relating to any alleged infringement of the patent, or to the validity or enforceability of the patent.
- 7) The attorneys from your outside law firm will acknowledge in writing their receipt of a copy of these terms and restrictions prior to production of any



Confidential Apotex Information. Such written acknowledgement shall be provided to Apotex.

- 8) This Offer of confidential Access shall be governed by the laws of the State of Illinois.

Section 355(j)(5)(C)(i)(III) of the Act provides that any request for access that you make under this Offer of Confidential Access "shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in [this] offer of confidential access" and that the "restrictions and other terms of [this] offer of confidential access shall be considered terms of an enforceable contract." Thus, to the extent that you request access to Confidential Apotex Information, you necessarily accept the terms and restrictions outlined above. Written notice requesting access under this Offer of Confidential Access should be made to:

Ms. Tammy McIntire  
Apotex Corp.  
2400 N. Commerce Parkway  
Suite 400  
Weston, FLA 33326

By providing this Offer of Confidential Access to Application, Apotex maintains the right and ability to bring a Declaratory Judgment action under 28 U.S.C. §§ 2201 et seq., pursuant to 21 U.S.C. § 355(j)(5)(C).

Yours very truly,

APOTEX INC.

Bernard C. Sherman, Ph.D., P.Eng.  
Chairman and C.E.O.

BCS/jm

**CERTIFICATE OF SERVICE**

I hereby certify that on the 30th day of May, 2006, the attached **NOTICE OF DEPOSITION AND SUBPOENA OF APOTEX INC. PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 45** was served upon the below-named counsel of record at the address and in the manner indicated:

John W. Shaw, Esquire  
Young Conaway Stargatt & Taylor, LLP  
The Brandywine Building  
1000 West Street, 17<sup>th</sup> Floor  
Wilmington, DE 19801

HAND DELIVERY

Daniel F. Attridge, P.C.  
Kirkland & Ellis LLP  
655 15<sup>th</sup> Street, N.W.  
Washington, DC 20005-5793

VIA FEDERAL EXPRESS

Mary B. Matterer, Esquire  
Morris James Hitchens & Williams LLP  
222 Delaware Avenue, 10<sup>th</sup> Floor  
Wilmington, DE 19801

HAND DELIVERY

William A. Rakoczy, Esquire  
Rakoczy Molino Mazzochi Siwik LLP  
6 West Hubbard Street, Suite 500  
Chicago, IL 60601

VIA FEDERAL EXPRESS

Richard L. Horwitz, Esquire  
Potter Anderson & Corroon LLP  
Hercules Plaza, 6<sup>th</sup> Floor  
1313 N. Market Street  
P.O. Box 951  
Wilmington, DE 19899

HAND DELIVERY

Stuart D. Sender, Esquire  
Budd Lerner, P.C.  
150 John F. Kennedy Parkway  
Short Hills, NJ 07078

VIA FEDERAL EXPRESS

John C. Phillips, Jr., Esquire  
Phillips, Goldman & Spence, P.A.  
1200 North Broom Street  
Wilmington, DE 19806

HAND DELIVERY

Lynn M. Ulrich, Esquire  
Winston & Strawn LLP  
35 West Wacker Drive  
Chicago, IL 60601

VIA FEDERAL EXPRESS

Frederick L. Cottrell, III, Esquire  
Richards, Layton & Finger  
One Rodney Square  
Wilmington, DE 19801

HAND DELIVERY

Alan H. Bernstein, Esquire  
Caesar, Rivise, Bernstein, Cohen & Pokotilow, Ltd.  
1635 Market Street, 12<sup>th</sup> Floor  
Philadelphia, PA 19103

VIA FEDERAL EXPRESS

*/s/ Tiffany Geyer Lydon*

---

Tiffany Geyer Lydon